A Supplement to

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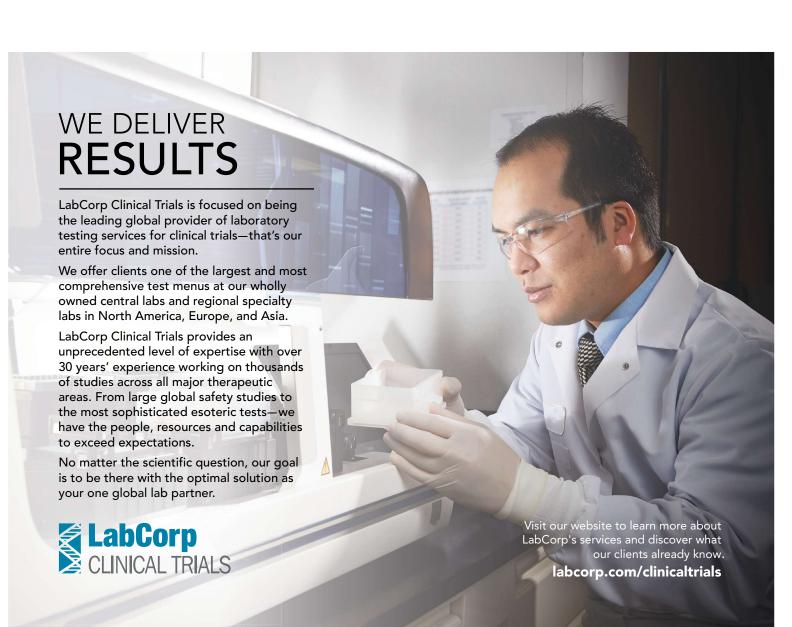


science

noun /ˈsīə ns/

- 1: LabCorp Clinical Trials delivers high quality and cutting-edge science in multiple areas such as biomarker development, flow cytometry, and companion diagnostics.
- 2: We also provide a number of core genomic services to our clients including mutation analysis, pharmacogenetics and pharmacogenomics from our global locations in North America, Belgium, Singapore and China to support early to late phase clinical trials.
- 3: LabCorp recently acquired the Covance
 Genomics Laboratory and its associated
 genomic analysis business located in Seattle.
 This state-of-the-art laboratory has significantly
 expanded our offering by allowing LabCorp to
 provide leading-edge complex genomic
 analysis including gene expression array
 studies, biomarker translation, and next
 generation sequencing applications.
- 4: As a result, LabCorp is now one of the few global providers offering such a comprehensive portfolio of core and advanced genomic services, supporting clients from preclinical and early stage to late stage drug development.





A Supplement to

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FEATURE

The Continued Evolution
Of The Sponsor-CRO
Relationship 12

Sponsors rely on CROs for their expertise in complex projects

FEATURE

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Long term, win-win commitments shouldn't be limited to full-service CROs

FEATURE

The Importance Of Reevaluating The Preferred Vendor List **24**

Changes in upper management or project staff can impact CRO performance and satisfaction

PLUS

The Latest Industry Trends And Proprietary Data From Nice Insight Survey Results



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AUGUST 2014 CRO SUPPLEMENT VOL. 6 NO. 8



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Use Data To Find And Manage Your CRO Partnerships



ED MISETA Executive Editor



ata is everywhere, and its importance in today's world cannot be overstated. Oracle president Mark Hurd recently noted there will be as much data created in the next

year and a half as has been created in the entire history of the planet. Add to that the fact that data is also now coming in from many sources that didn't exist in the past. According to Hurd, there are currently 9 billion devices connected to the Internet, a number that may reach 50 billion by the end of the decade. This will create an absolute explosion of data that businesses, including those in the life sciences, will have to manage. We know going in that a lot of that data will be worthless. Therefore, it will be incumbent upon companies to discern the valuable data from the noise.

Having data is just one part of the equation. Understanding it and properly analyzing it is another. Jeff Baker, deputy director, Office of Biotechnology Products, CDER at the FDA, recently said, "There's a big difference between data analysis and knowledge management. Data analysis yields information; knowledge management tells you what to do with this information. Business hasn't learned to link knowledge management to risk." His point is clear: Simply having access to large amounts of data doesn't do us a lot of good if we don't know what to do with it.

Having an abundance of data can be very helpful (provided we know how to properly analyze it) when selecting the right partners to trust with your outsourced clinical trials and manufacturing. For that information, we at Life Science Leader turn to our partners at Nice Insight.

We all know the relationship between pharma and CROs is changing. Some firms still use the transactional approach of outsourcing a specific aspect of a clinical trial to a specific vendor. Others have jumped on the strategic relationship model where both the vendor and the CRO have a larger investment in their respective partners. Of course, this latter model will place considerably more importance on the process of selecting a partner. Still other companies will use a combination of the approaches, depending on the study under consideration. By looking at available data on what companies are doing, as well as why they are doing it, outsourcers will be able to make better decisions regarding what approach is best for them.

Once you have landed on the right course of action, you still have to select a partner. Here again, data, especially data collected from your peers, can greatly simplify the selection process. How do other pharma companies view their service providers when it comes to quality? Timeliness? Cost? Regulatory compliance? This information can be incredibly valuable when it comes to making choices.

Finally, once you have a list of preferred providers, how do you know if anything has changed at that vendor that could change the dynamic of your relationship? Has a recent merger or acquisition affected the CRO's ability to conduct your study? How would you know this? Timely and accurate data is again the answer.

In compiling this issue, Nice Insight meticulously gathered and analyzed the data contained on these pages, and we present it here to assist you in your decision-making process. I hope you will enjoy this special issue devoted to the pharma/CRO relationship. Andy Dahlem, VP of Lilly Research Laboratories' (LRL) operations and LRL Europe, once told me, "When I make a deal with a service provider to do the work, it's my reputation that is at risk. That is not a responsibility I take lightly." Hopefully after absorbing the information in this issue, you will feel a lot more at ease when putting your own reputation on the line.

-Life Science 🕇

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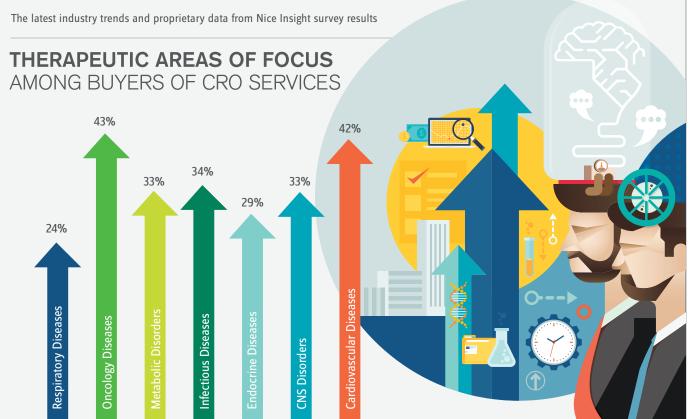


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OPTIMIZING **SPONSOR/CRO**COLLABORATIONS



▶ SINCE ITS INCEPTION, the primary goal of Nice Insight's Pharmaceutical and Biotechnology Outsourcing Survey has been to optimize collaborations between CROs/CMOs and sponsor organizations. The benefits of improved collaborations play out in many forms and offer advantages every step of the way – from reduced costs, improved staff efficiencies, and increased shareholder value all the way to more affordable medicines for consumers. Outsourcing Insights has been a platform for Nice Insight to share some simple strategies on how to get the best results from an outsourcing relationship, whether that relationship is tactical, with a preferred vendor, or a strategic partnership. Each of these different types of outsourcing relationships has its merits, and, not surprisingly, most sponsor organizations engage CROs that fall into each category.



RESPONDENT **PROFILE INFORMATION**

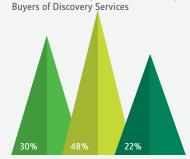
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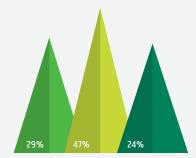
BY **COMPANY TYPE**



BY ANNUAL OUTSOURCING EXPENDITURE

■ Less than 10M USD per year ■ 10 to 50M USD per year ■ 50M+ USD per year Annual Outsourcing Expenditure Among Annual Outsourcing Expenditure Overall





BY **REGION**





FUROPF



Respondents who buy CRO services and outsource discovery phase average 2.65 different therapeutic areas of focus for outsourced projects in the next 12 to 18 months

Respondents who buy CRO services and outsource discovery are looking to outsource an average of 5.9 different services in the next 12 to 18 months

METHODS USED TO IDENTIFY **OUTSOURCING PARTNERS**



AVERAGE # OF METHODS USED TO IDENTIFY A CRO



Industry Research



Referrals & Colleagues





Periodicals & **Publications**



Web Searches





88%

88%

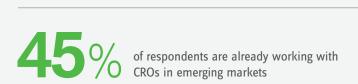
87%

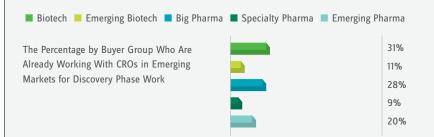
75% 78%

OUTSOURCING TO EMERGING MARKETS AMONG **DISCOVERY PHASE BUYERS** OF CRO SERVICES











DISCOVERY PHASE WORK OUTSOURCED

The Percentage of Respondents Who Outsource Discovery Engage a CRO for the Following Activities

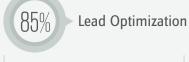
















54% 21% 80%



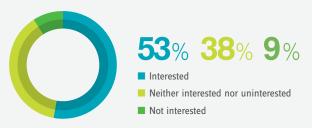
OUTSOURCING PREFERENCES & PRACTICES AMONG BUYERS OF DISCOVERY PHASE CRO SERVICES

OUTSOURCING RELATIONSHIPS

% of projects contracted to each type of outsourcing relationship



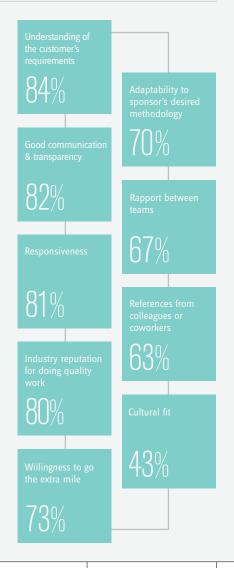
INTEREST LEVEL IN A STRATEGIC PARTNERSHIP

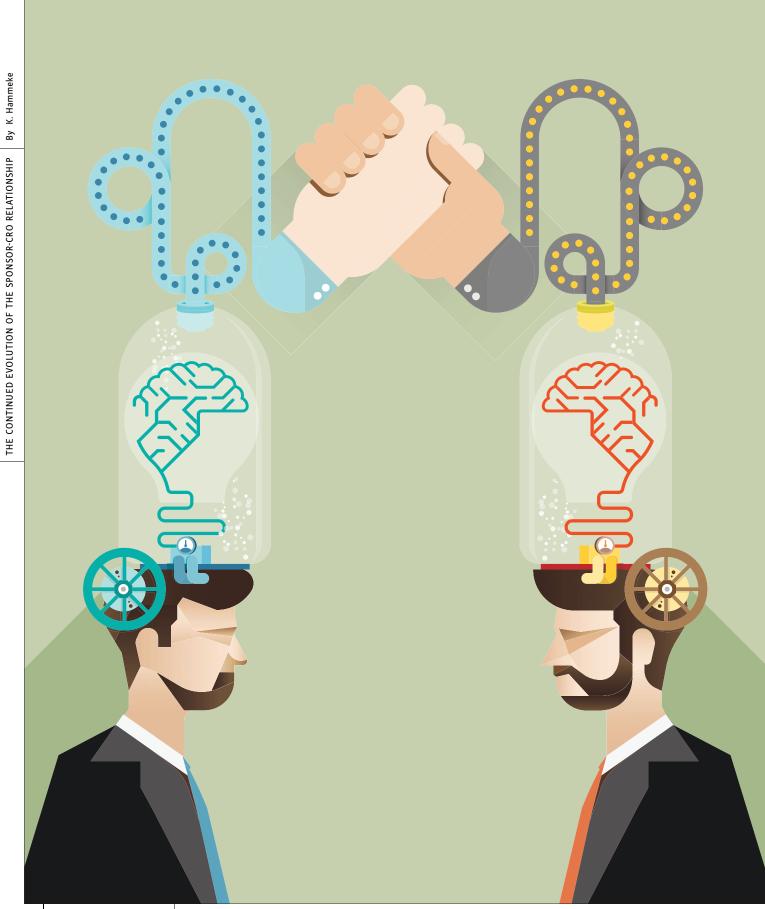














OUTSOURCING DISCOVERY PHASE TRENDS

The Continued Evolution Of The Sponsor-CRO Relationship

Not long ago, the dynamic between the sponsor and the CRO was purely that of a client/vendor. Contract research organizations were engaged to reduce fixed labor costs on the sponsor side for work that varied in demand.

KATE HAMMEKE Contributing Editor

- Contact Kate Hammeke at kate.h@thatsnice.com
- If you want to learn more about the report, please go to www.niceinsight.com

AT THE TIME, THE FOCUS WAS controlling capacity fluctuations that impacted overall profitability, the work assigned to contractors was commoditized and not directly involved with the generation of intellectual property, and the majority of contracts went to businesses in the U.S. and EU. Ultimately, the opportunity for savings didn't pan out as desired because hiring out mass production of unspecialized products didn't provide much of an advantage — the expense of subcontracting was comparable to doing the work in-house.

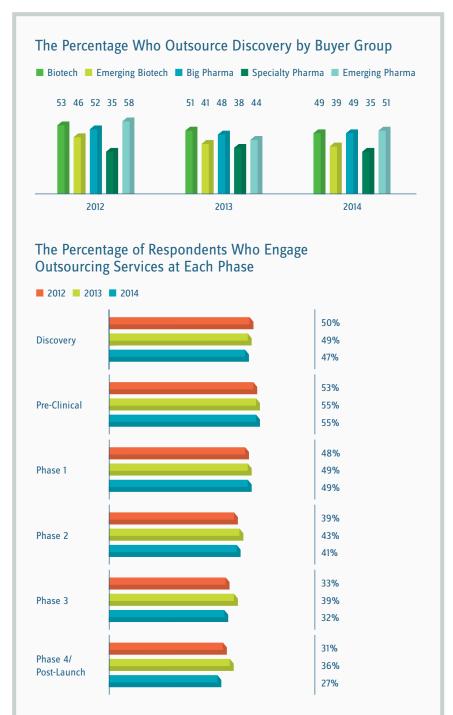
The true opportunity for savings through outsourcing started to take shape in the early part of the 21st century. Developing countries with strong education systems relaxed their trade borders around the same time that China and India started to strengthen patent laws. While some pharmaceutical companies opted to open their own research facilities overseas, others sought out CROs in these emerging markets. Within a few years, the amount of work and the complexity of the projects increased. The tipping point in the shift of the dynamic between sponsor and CRO from a client/vendor relationship to a partnership — with shared goals, transparent strategies, and mutual trust — occurred when some CROs started to expand their service offering to include discovery programs.

The results from Nice Insight's annual survey show that the practice of outsourcing discovery remains common, with only a slight fluctuation in popularity over the past three years, from 50 percent in 2012 to 47 percent in 2014. Discovery is now the third most popular phase during which sponsors engage outsourcing services, after preclinical (55 percent) and Phase 1 (49 percent). The likelihood of engaging outsourcing services decreases somewhat through the subsequent phases, from 41 percent for Phase 2, 32 percent for Phase 3, and 27 percent for Phase 4/Post-Launch studies.

Among the different sponsor segments, there was some variation in the frequency of outsourcing services for discovery phase work. However, each sponsor segment showed a strong preference for using a global, full-service CRO rather than a local, full-service CRO or a specialty CRO. Interestingly, emerging pharma companies are the most likely to outsource discovery, with 51 percent of respondents indicating their company would engage services for this stage. Biotech and Big Pharma followed, each with 49 percent. Emerging biotech companies followed with 39 percent outsourcing discovery, and approximately one-third of specialty pharma companies (35 percent) engage outsourcing services during this phase of the drug cycle. Traditional pharmaceutical companies tend to outsource discovery phase work with a greater frequency than biotech companies.

Secondary industry research supports the notion that outsourcing discovery





Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2013-2014 report includes responses from 2,337 participants. The survey is comprised of 240+ questions and randomly presents ~35 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions of the top 100+ CMOs and top 50+ CROs servicing the drug development cycle. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory Track Record, Affordability, Productivity, and Reliability. In addition to measuring customer awareness and perception information on specific companies, the survey collects data on general outsourcing practices and preferences as well as barriers to strategic partnerships among buyers of outsourced services.

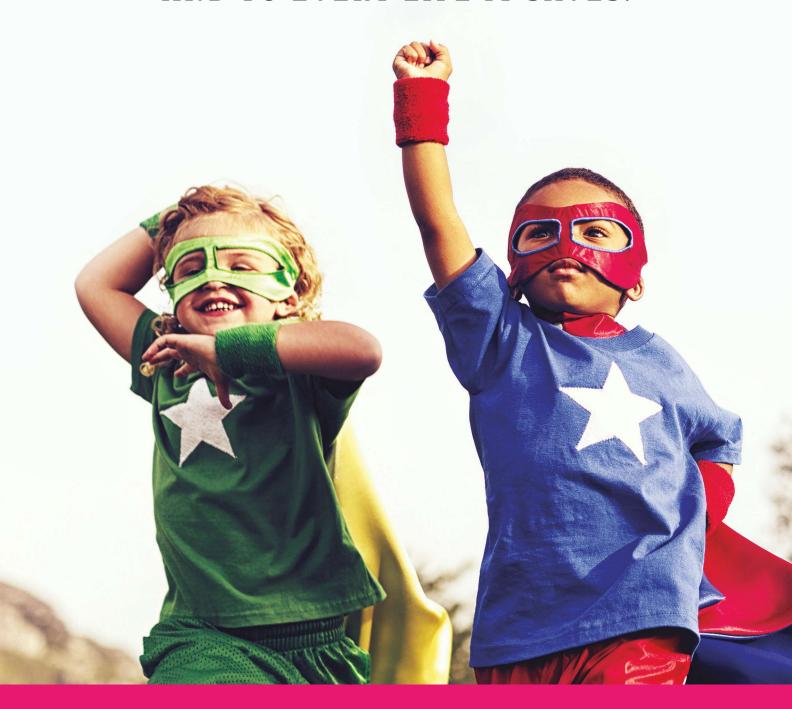
improves lead optimization, which is crucial to ensuring a strong pipeline. And, among those who reported their company outsources discovery phase projects, 93 percent sought target ID and validation services, and 94 percent looked for lead identification. Lead optimization and candidate selection followed, with 85 and 72 percent respectively. These figures have remained consistent across discovery-focused outsourcing surveys over the past three years. The specific capabilities within these categories have evolved somewhat, in that skills previously identified as "future expectations" have shifted to "current expectations."

It is still too early to know how successful the practice of engaging a CRO for discovery will be when it comes to accelerating new drugs to market. But current practices, combined with some ambitious activity among global, full-service CROs (in the acquisition of smaller, discovery-centric businesses), suggest the practice of outsourcing discovery will continue to push the evolution of the sponsor-CRO relationship, which will have a positive impact on drug development.



Kate is the director of marketing intelligence for Nice Insight, the research division of That's Nice. Kate runs all custom market research for the company, and she designed the first industrywide study on selecting outsourcing partners during the drug development cycle for the Pharmaceutical and Biotechnology sector. Kate continues to update the Nice Insight CRO/CMO research according to evolving industry trends, and she works on the development of Nice Insight's new subscription product on the excipients market. Kate has developed and coordinated custom research projects for more than 30 major brands in the Fortune 500. Based on her industry knowledge, Kate has written dozens of articles related to pharmaceutical outsourcing for five industry magazines. She is a monthly contributor to Life Science Leader magazine, authoring the column "Outsourcing Insights."

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STRATEGIC PARTNERING TRENDS

A Combination of Functional And Full-Service CROs Supports Strategic Outsourcing

Outsourcing has become part of the strategy of just about every business in the drug development industry. Subcontracting various procedures along the stages of development to outside firms adds value to the process by reducing fixed costs, shortening timelines, and offering access to external expertise.

KATE HAMMEKE **Contributing Editor**

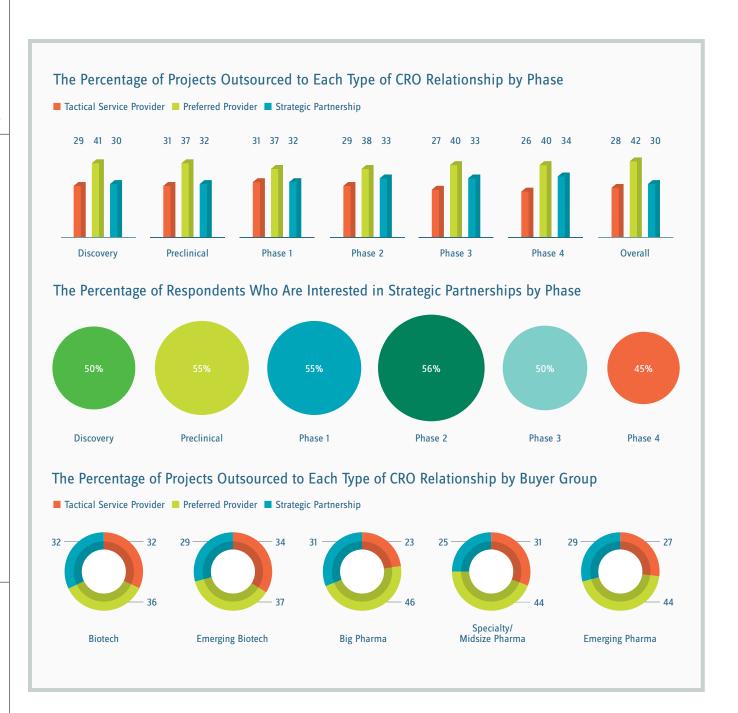
- Contact Kate Hammeke at kate.h@thatsnice.com
- If you want to learn more about the report, please go to www.niceinsight.com

▶ AS OUTSOURCING HAS MOVED from being viewed as an option to reduce costs to being integral to drug development strategy, the term "strategic outsourcing" can be applied to almost any method of engaging outside providers, whether it is for a single element of the process or multiple steps along the way.

There are benefits and shortcomings to the three main types of outsourcing relationships - tactical service provider, preferred provider, and strategic partnership - and most contract relationships fall somewhere between a one-off job and a long-term, mutually beneficial relationship. The decision of whether to engage functional service providers for tactical needs or pair up with a full-service provider that can assist with a broader range of activities comes through evaluating the needs for a specific project coupled with the long-term needs and goals of the sponsor organization. However, understanding some benefits and disadvantages of each - in addition to learning what has worked for similar businesses — can offer insight into which practices will bring the most value to your firm.

Functional or specialty CROs that offer a limited range of services and have expertise in a specific therapeutic area, methodology, or service are often best used for their ability to deliver on tactical projects. These companies may be local or global, and add value to sponsor organizations through access to expertise while at the same time retaining control over the process. Since this type of provider has a limited service offering or capacity, they continue to fulfill a very important role, but may not be top of mind for a strategic partnership-unless your company possesses a significant need for the niche offering. Sponsors tend to use tactical service providers for just under one-third of their outsourced projects, regardless of phase of development. When a CRO starts off as a tactical provider, there is a good chance the CRO will have the opportunity for the relationship to escalate to that of a preferred provider.

Many outsourcers think only of full-service CROs — ones that offer a complete range of services from preclinical development through marketing - when envisioning a strategic partner. Full-service CROs oftentimes enable a sponsor organization to have a single point of contact for multiple outsourced needs. A single point of contact can minimize frustrations related to miscommunication, misunderstood priorities, and delays associated with decision making. Partnerships with full-service CROs can decrease the necessary resources allocated to managing multiple vendors as well as the expense of vetting multiple





If you want to learn more about the report or how to participate, please contact Nigel Walker, managing director, or Kate Hammeke, director of marketing intelligence, at Nice Insight by sending an email to nigel@thatsnice.com or kate.h@thatsnice.com.

Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2013-2014 report includes responses from 2,337 participants. The survey comprises 240+ questions and randomly presents ~35 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions of the top 100+ CMOs and top 50+ CROs servicing the drug development cycle. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory Track Record, Affordability, Productivity, and Reliability. In addition to measuring customer awareness and perception information on specific companies, the survey collects data on general outsourcing practices and preferences as well as barriers to strategic partnerships among buyers of outsourced services.



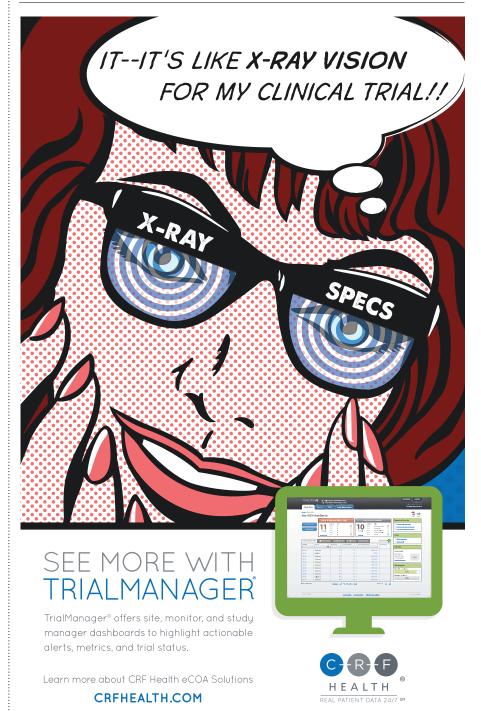
outsourcing strategy
that combines functional
and full-service CROs based
on the best fit for projects
means that your plan will
include all three types of
outsourcing relationships
— tactical service providers,
preferred providers, and
strategic partnerships.

suppliers. On the flip side, a full-service CRO created through acquisitions may be a hodgepodge of dissimilar business units scattered across the globe where there is no guarantee of integration or communication across locations and cultures, despite standing as one brand.

Nice Insight research has shown outsourcing preferences frequently vary across different buyer groups, and this remains true in how sponsors distribute projects to tactical service providers, preferred providers, and strategic partners. When it comes to engaging CROs, Big Pharma allocates the smallest percentage of projects to tactical providers (23 percent) and the greatest percentage go to preferred providers (46 percent). Emerging pharma allocates projects similarly, with 27 percent of projects assigned tactically and 44 percent to companies on the preferred provider list. Specialty pharma companies relied heavily on the preferred provider list. similar to big and emerging pharma companies. They also allocated the fewest projects to strategic partners, with only 25 percent going towards this type of CRO relationship. Biotechs and emerging biotechs tend to distribute approximately one-third of projects to each type of CRO relationship.

Developing an outsourcing strategy that combines functional and full-service CROs based on the best fit for projects means that your plan will include all three types of outsourcing relationships — tactical service providers, preferred

providers, and strategic partnerships. Considering future goals and needs, as well as gaining insight through understanding what has worked for industry peers can help with more informed strategic decisions to address present needs. 1



RESPONDENT **PROFILE INFORMATION**

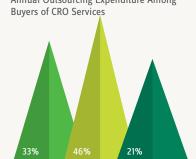
Research conducted by Nice Insight [n=332]

BY **COMPANY TYPE**



BY ANNUAL OUTSOURCING EXPENDITURE

■ Less than 10M USD per year ■ 10 to 50M USD per year ■ 50M+ USD per year Annual Outsourcing Expenditure Among Annual Outsourcing Expenditure Overall





BY **REGION**





FUROPF



Respondents who buy CRO services average 2.5 different therapeutic areas of focus for outsourced projects in the next 12 to 18 months

DIFFERENT SERVICES

Respondents who buy CRO services are looking to outsource an average of 4.9 different services in the next 12 to 18 months

METHODS USED TO IDENTIFY **OUTSOURCING PARTNERS**



AVERAGE # OF METHODS USED TO IDENTIFY A CRO









Trade Shows



Periodicals &

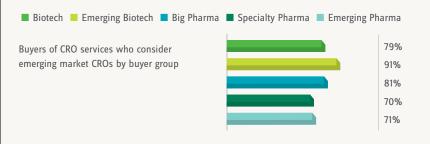






OUTSOURCING TO EMERGING MARKETS AMONG BUYERS OF CRO SERVICES

of respondents will consider CROs in emerging markets



of respondents are already working with CROs in emerging markets



■ Biotech ■ Emerging Biotech ■ Big Pharma ■ Specialty Pharma ■ Emerging Pharma

of respondents say the quality level is too risky to offshore projects

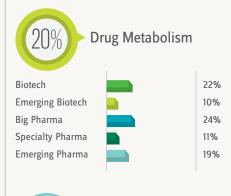
Biotech Emerging Biotech Big Pharma Specialty Pharma Emerging Pharma

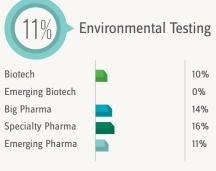
The percentage by buyer group who believe the quality level is too risky to offshore CRO services

SERVICES OUTSOURCED AMONG CRO BUYERS

The Percentage of Respondents Who Outsource the Following Services to Emerging Market CROs by Buyer Group











OUTSOURCING PREFERENCES & PRACTICES **AMONG BUYERS OF CRO SERVICES**

OUTSOURCING RELATIONSHIPS

% of projects contracted to each type of outsourcing relationship

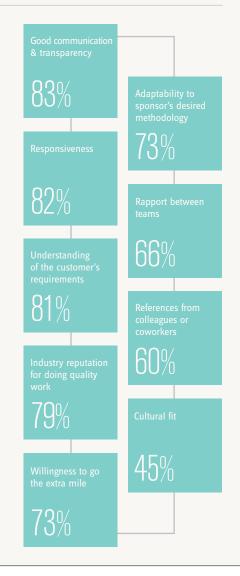


INTEREST LEVEL IN A STRATEGIC PARTNERSHIP

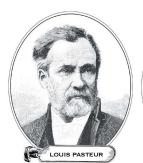








Compare impartial peer reviews to find the ideal CRO



Company No. 1 New clinical trial awarded to established CRO

Start date delayed due to recruitment challenge



Company No. 2

Preclinical primate study awarded to US domestic CRO

Candidate stress identified in transported colony



Company No. 3

New indication identified through extended study

CRO unable to handle increased study demands



Company No. 4

New indication announced by drug innovator

Pressure on clinical supply



Company No. 5

Public biotech demands robust protocol

Transactional PK pricing drives down price

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Nice Insight is unique in enabling you to compare a large number of CROs based on impartial reviews from thousands of respected peers that buy outsourced services, rather than relying on the typical claims that make them all appear the same. Learn who is rated highest for the leading drivers: quality, reliability, regulatory, affordability, productivity and innovation — and quickly establish a shortlist that best aligns with your strategy.

Search. Compare. Contact.

For more information, contact Nigel Walker, Managing Director at nigel@thatsnice.com or +1 212 366 4455.

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The Importance Of Reevaluating The Preferred Vendor List:

Mergers & Acquisitions Often Impact CRO Performance

Biopharmaceutical companies with preferred provider lists should have an internal system to gather feedback throughout the course of the project and after its completion. However, internal feedback should not be the only basis for evaluation of companies on the preferred vendor list.

KATE HAMMEKE Contributing Editor

Contact Kate Hammeke at kate.h@thatsnice.com

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OUTSIDE FACTORS CAN INFLUENCE how a contract research organization operates, ranging from the exit or promotion of a key staff member to a significant change in operations or personnel due to a merger or acquisition.

Four CROs included in Nice Insight's annual research merged with or were acquired by other contract research companies in 2011. Three years on, it is time to check how the newly formed CROs have fared now that they have integrated new staff and had a sufficient amount of time to adjust to the changes that accompany a merger or acquisition. The companies under review are: INC Research/Kendle, Agilent/Biocius, Inventive Health/Pharma-Net, and Eurofins Lancaster/Lancaster Labs.

Productivity is a key outsourcing driver, as it contributes to the sponsor's ability to help speed the product to market. If an acquisition results in a decline in customer perception for productivity — a metric continuously monitored by Nice Insight - it indicates that the business should be reevaluated to mitigate issues relating to the change in perception. Each of these CROs' scores slipped in productivity postintegration and still have not fully recovered. Inventiv Health showed the largest drop in the category (down five percentage points) relative to PharmaNet's score in 2011. Agilent also struggles to maintain the positive perception Biocius possessed in productivity, down four percent from the 2011 rating. Both INC Research and Eurofins Lancaster fared better, with only a two percentage point decrease from prior productivity ratings.

Not surprisingly, preserving one's regulatory track record can be difficult through major changes to the structure of the business. This category experienced the largest downward shifts in customer perception after an acquisition, with each CRO falling between five and seven percentage points in customer perception. Quality has been the top-ranking criteria for CRO partner selection the past four years running, and maintaining quality post-M&A should be the top priority for businesses going through this transition. Yet it seems this is one of the more difficult customer perceptions to uphold years later, despite the heavy focus on its importance. Eurofins Lancaster fared the best in this category, despite dropping one percentage point, as their quality score (74 percent) was the highest of the group.

A CRO's reliability — or ability to meet all project milestones and timelines — is essential to keeping a study on track and within budget. A change in a company's reliability score warrants investigation, as the ability to maintain timelines directly impacts the sponsors' ability to deliver. While none of the CROs made significant improvements in reliability postmerger, Eurofins Lancaster and Agilent maintained their reliability ratings; conversely INC Research's and Inventiv Health's scores slipped (8 and 4



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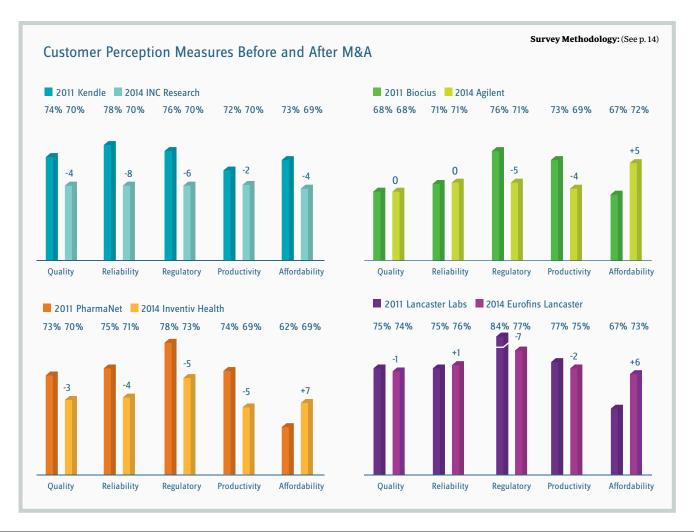
percentage points respectively).

The one customer perception measure where several of the newly formed CROs show noteworthy positive shifts is affordability. Inventiv Health, Eurofins Lancaster, and Agilent have all improved

their affordability scores by five or more percentage points. While affordability is an important attribute, it has fallen in rank in the past four years, from third to fifth place. And when asked about how price factors into CRO strategic partner selection criteria, it is often iterated that when quality and reliability measures show parity, cost comes into play. Otherwise, price is seldom used as a differentiating factor. Therefore, improved customer perception in affordability is not a good reason to keep a CRO on the preferred vendor list, especially when affordability comes at the expense of another customer perception attribute.

These findings suggests that when one of the CROs on your company's preferred vendor list is acquired by another CRO — even if it is another business on your preferred vendor list — the sponsor's

procurement staff should reevaluate the new entity to ensure it still meets the criteria of a preferred vendor. Monitoring companies on the provider list to see if they have undergone significant changes in structure or staff is a good first line of assessment. Next, opinions gathered via word of mouth from colleagues should be considered. Lastly, a review of how the business is rated among industry peers - measuring pre- and postchange - will provide fundamental ongoing due diligence. In the past year there have been a number of notable acquisitions among CROs - PRA International's merger with RPS, Huntingdon's purchase of Harlan Labs, and Icon's acquisition of Aptiv Solutions. Keeping an eye on how these businesses perform in the coming years will be important to preserving a solid preferred vendor list.





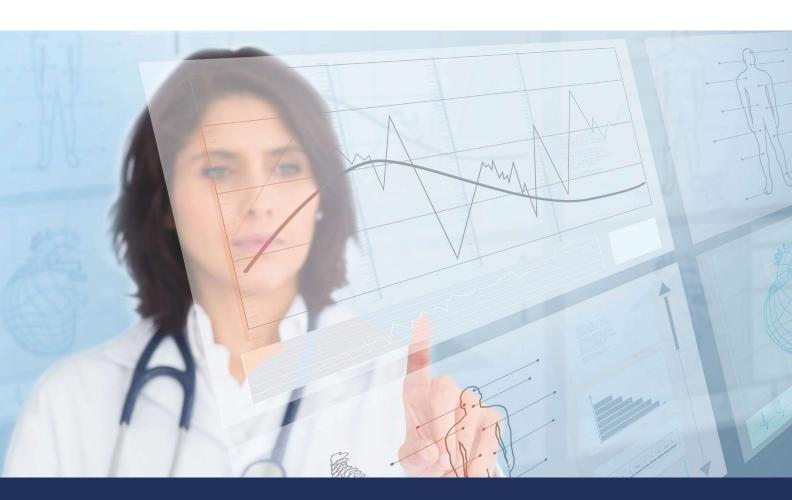
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